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November 1, 2024

VIA ECF

Honorable Cathy L. Waldor, U.S.M.J.
United States District Court
District of New Jersey
Martin Luther King Building & U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07102

Re: *In re Selenious Acid Litigation*, C.A. No. 24-cv-7791 (BRM)(CLW) (consolidated)

Dear Judge Waldor:

Pursuant to Paragraph 7 of the Court's Civil Case Management Order, Plaintiff American Regent, Inc. ("ARI") and Defendants in the above-captioned matters submit this joint letter seeking resolution of the parties' dispute regarding a Pretrial Scheduling Order.

* * *

I. Efforts to Resolve the Dispute

a. ARI's Position

On August 29, 2024, ARI sent an email to each Defendant notifying them that ARI would be seeking an expedited schedule in these actions due to, *inter alia*, uncertainty over whether or not there is a 30-month stay of FDA approval for the ANDAs at issue. *See, e.g.*, Ex. A (Aug. 29, 2024 Email from R. Conkin to K. Mathas). ARI included its proposed schedule and requested feedback on the schedule by September 3, 2024. ARI received Defendants' proposed schedule on September 20, 2024. ARI informed Defendants that their proposed schedule is not feasible given the current posture of these matters and the lack of a 30-month stay. ARI subsequently requested that the parties meet and confer so that ARI could seek relief from the Court. *See* Ex. B (Sept. 25, 2024 Email from R. Conkin to M. Stubbings). ARI additionally informed Defendants that it intended to modify its proposed schedule to include deadlines related to potential preliminary injunction briefing. *Id.* The parties met and conferred on September 26, 2024, where Defendants stated they would not agree to an expedited schedule or ARI's additions regarding preliminary injunction briefing. Thus, the parties are at an impasse. ARI's and Defendants' proposed schedule is attached to this letter as Exhibit C.

By agreement of the parties, ARI served its disclosure of asserted claims regarding the '565 patent pursuant to L. Pat. R. 3.6(b) on October 14, 2024. Moreover, the parties exchanged initial disclosures pursuant to Fed. R. Civ. P. 26(a)(1) on October 18, 2024.[1]

b. Defendants' Position

Although ARI accuses Defendants of delaying negotiations related to ARI's unnecessarily quick schedule, ARI itself has moved with a lack of urgency. Specifically, ARI provided its initial draft of this joint letter to Defendants on October 8, 2024—nearly two weeks after the parties met and conferred—along with a revised version of its proposed schedule. Then, on October 11, 2024, ARI notified Defendants of a notice of allowance for yet another patent that may impact this litigation, despite receiving the initial notice of allowance for this same patent on September 5, 2024, before the application published on September 26, 2024.[2] At that time, ARI asked Defendants to stipulate to the filing of an amended complaint adding that patent and explained they would follow up with a second revised schedule. ARI did not send its second revision until October 18, 2024. Regardless, that revised schedule would have this Court and the parties trying two patents—one of which is already asserted in an earlier case and the second of which the PTO has not yet even issued—in less than a year. In contrast, and as explained below, Defendants' proposed schedule conserves judicial resources to avoid duplicative trials on identical patents across this case and co-pending litigation related to Tralement® and Multrys®. *See* Section III.

II. ARI's Position

A. An expedited schedule is warranted

An expedited schedule is warranted for these matters primarily because the vast majority of Defendants are not subject to a 30-month stay of FDA approval. The lack of a 30-month stay stems from the fact that the Asserted Patent did not list in the Orange Book until after most Defendants filed their ANDAs. Since there is no 30-month stay for most of the Defendants, it raises the possibility that one or more Defendant will commercially launch the accused ANDA product "at-risk" prior to a decision from this Court and immediately upon FDA approval, which

[1] ARI and Fresenius Kabi USA, LLC ("Fresenius") have not exchanged initial disclosures pursuant to Fed. R. Civ. P. 26(a)(1) based, in part, on Fresenius's pending pre-motion letter and the parties' ongoing discussions.

[2] Between the initial Notice of Allowance sent on September 5 and the October 9 Notice of Allowance, the only thing that occurred was that Plaintiff filed an Information Disclosure Statement ("IDS") attaching more than 20 new references without any explanation of why these references were being presented at all, much less explaining why they were only being presented after the initial Notice of Allowance. Approximately a week after the IDS was filed, the Examiner provided a Second Notice of Allowance without specific comment on any of the newly disclosed references, other than to sign off on the IDS.

may happen at any time.[3] In fact, some Defendants have openly stated that they intend to launch at risk and/or will not provide 60-day notice prior to any at-risk launch. Thus, absent some agreement by Defendants not to commence their pre-market activities and not to launch pending a resolution of these actions via an expedited trial schedule or otherwise, ARI will need to seek a preliminary injunction against all Defendants that are not subject to a 30-month stay in sufficient time to prevent what will, no doubt, be significant and irreparable harm.

Recognizing the burden such a motion would place on the Court and the parties, ARI proposed a schedule based on an expedited schedule previously entered by Your Honor in a case with similar positioning. *See Sumitomo Dainippon Pharma Co., Ltd. v. Emcure Pharms. Ltd.*, C.A. No. 18-cv-02065, ECF No. 25 (D.N.J. Apr. 19, 2018). However, after much delay, Defendants proposed a prolonged schedule that guarantees that the parties will need to burden the Court with extensive preliminary injunction motion practice as to many Defendants. ARI's expedited schedule seeks to *avoid*, or at least *minimize*, the number of preliminary injunction motions this Court will need to hear and provide deadlines for an orderly briefing schedule for those motions. On the other hand, Defendants' schedule will likely require the Court to decide preliminary injunction motions for most (if not all) Defendants without notice as they receive FDA approval.

Defendants incorrectly claim that ARI has moved "without urgency" in bringing this case. Not so. ARI began receiving notice letters for the '565 patent in early June; however, ARI continued to receive notice letters until late June, with the last notice letter of the first wave being dated June 27, 2024.[4] Yet, after ARI began to receive notice letters, ARI prepared and filed 14 complaints against 14 distinct defendant groups in just over a month.[5] Moreover, ARI took just over *two weeks* to file these complaints after receiving the final notice letter. Far from delaying, ARI has moved as efficiently as possible given the large number of Defendants in these actions.[6]

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[3] Despite Defendants' suggestion to the contrary (*see infra* at n.10), the goal dates for Defendants' ANDAs provide the latest date by which FDA must take action on the ANDA. *See* https://www.fda.gov/industry/generic-drug-user-fee-amendments/gdufa-ii-submission-review#:~:text=Original%20ANDAs&text=Within%2010%20months%20of%20submission%20date.&text=Within%208%20months%2C%20provided%20the,* (listing the goal date for "Standard Original ANDAs" as "*[w]ithin* 10 months of submission date") (emphasis added). Meaning the FDA could take action on Defendants' ANDAs anytime on *or before* that date.

[4] Defendant Eugia's notice letter was not received until early August and is dated August 5, 2024.

[5] In fact, ARI filed its complaints well within 45 days of receiving each notice letter as would be required to enact the 30-month stay of FDA approval, despite the stay not being available. *See* 21 U.S.C. § 355(c)(3)(C).

[6] For the first time on October 24, 2024 when providing their position for this letter, Defendants raised concerns that ARI has not circulated a Joint Discovery Plan. The parties have been engaged in negotiations for over two months, yet this is the first time Defendants have expressed a desire

Finally, ARI notified Defendants about the additional patent it seeks to assert merely two days after ARI received the notice of allowance, not "weeks" as Defendants now claim. *See* Ex. D (Notice of Allowance); Ex. E (Oct. 11, 2024 Email from R. Conkin to Defendants).

The Court is well within its authority to order an expedited schedule. "[D]istrict courts have the inherent authority to manage their dockets and courtrooms with a view toward the efficient and expedient resolution of cases." *Dietz v. Bouldin*, 579 U.S. 40, 47 (2016). Furthermore, L. Pat. R. 1.3 states "[t]he Court may modify the obligations or deadlines set forth in these Local Patent Rules based on *the circumstances of any particular case*, including, without limitation, the simplicity or complexity of the case as shown by the patents, claims, products, or parties involved. Such modifications shall, in most cases, be made at the initial Scheduling Conference." (emphasis added). The circumstances here warrant an expedited schedule.

B. Deadlines regarding any potential preliminary injunction briefing are warranted

In addition to the expedited schedule, and given that Defendants will not agree to any advance notice of an at-risk launch, certain deadlines related to any potential preliminary injunction briefing are warranted in an effort to efficiently proceed should a preliminary injunction motion be necessary. Specifically, ARI proposes the following deadlines:

- On November 1, each Defendant group will indicate whether they will agree not to launch at risk until this Court's decision or otherwise agree to provide 60-day notice prior to any at-risk launch.

- On November 15 (or a date convenient for the Court), we will ask that the Court hold a status conference to discuss an orderly preliminary injunction briefing schedule for any Defendant group who does not agree to the request above.

- On November 8, the parties will submit a joint letter to the Court concerning the issues to be discussed at the November 15 status conference regarding the need for preliminary injunction briefing, and which Defendant groups will be participating in preliminary injunction motion practice.

Should preliminary injunction motions be necessary, the deadlines above will minimize the burden on the Court and allow the motions proceed in an organized and efficient manner. As above, this is well within the Court's authority to manage its docket. *See Dietz*, 579 U.S. at 47. In fact, courts in this District have previously entered scheduling orders with similar deadlines to avoid unnecessary adjudication by permitting defendants willing to commit to not launching at risk to opt out of the briefing associated with a preliminary injunction motion. *See Otsuka Pharma*

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to engage in discussions of discovery-related issues. Nonetheless, ARI will circulate a proposed Joint Discovery Plan as soon as possible.

Co., Ltd. v. Torrent Pharms. Ltd., Inc., C.A. No. 14-cv-01078, ECF No. 76 (D.N.J. March 17, 2015); *see also Medeva Pharma Suisse A.G. v. Roxane Lab'ys, Inc.*, C.A. No. 07-cv-5165, ECF No. 119 (D.N.J. Nov. 30, 2009) (ordering defendants to provide notice of launch at risk, finding that "issuing this requirement is within [the Court's] sound discretion to manage matters of docket control and scheduling (*Alaska v. Boise Cascade Corp.*, 685 F. 2d 810, 817 (3d Cir. 1982))").

C. These actions are separate and distinct from the co-pending litigation regarding ARI's Tralement® and Multrys®

During the parties' September 26 meet and confer, Defendants indicated that they believe the schedule in these matters (which involve Selenious Acid) should mirror the schedule in separate co-pending matters regarding entirely different products (ARI's Tralement® and Multrys® drug products).[7] The Tralement® and Multrys® matters are also Hatch-Waxman actions; however, they involve separate ANDAs filed by six defendants seeking approval for generic versions of ARI's Tralement® and Multrys® products. The Tralement® and Multrys® matters involve three patents, only one of which (U.S. Patent No. 11,998,565) is at issue in these cases. Other than that minor overlap, the Tralement®/Multrys® and these Selenious Acid matters involve different branded products, different ANDAs, and multiple different defendants.

Most importantly, the Tralement® and Multrys® cases do have a 30-month stay, so there is no risk for injunction practice currently, unlike these Selenious Acid cases. Defendants' attempt to conflate these Selenious Acid actions with the Tralement® and Multrys® matters is not practical, is not warranted, and prejudices ARI. Specifically, consolidating the schedule in these matters with the schedule entered in the Tralement®/Multrys® matters hinders the Court's ability to expeditiously try these cases, which, as explained above, virtually guarantees the need for preliminary injunction motions so that ARI can prevent significant and irreparable harm. Because all of the Tralement® and Multrys® matters are subject to a 30-month stay of FDA approval, unlike these cases, the slower schedule in the Tralement® and Multrys® matters does not risk irreparable harm to ARI and does not pose the same risk of burdening the Court with preliminary injunction motions. That is not so for these cases.

Defendants claim that trying the Selenious Acid matters on an expedited schedule "will result in significant inefficiencies and multiple trials on the same subject matter." *See infra* Section II.C. But it is the opposite. Five of the six Tralement®/Multrys® defendants are also Selenious Acid defendants. Thus, trying the validity of the '565 patent on an expedited schedule would streamline any trial in Tralement®/Multrys®, where the only remaining issues regarding the '565 patent would be infringement. The same analysis applies to ARI's newly issued patent. *See* Ex. D. Should ARI seek to add it to the Tralement®/Multrys® litigation, trying the validity of that patent in the

[7] *See American Regent, Inc. v. Somerset Therapeutics, LLC*, No. 2:24-cv-01022-BRM-CLW (consolidated); *American Regent, Inc. v. Gland Pharma Ltd.*, No. 2:24-cv-07756-BRM-CLW; *American Regent, Inc. v. Cipla USA, Inc.*, No. 2:24-cv-08435-BRM-CLW; *see American Regent, Inc. v. Accord Healthcare, Inc.*, No. 2:24-cv-09600-BRM-CLW.

Selenious Acid matters on an expedited schedule only streamlines the issues to be tried in the Tralement®/Multrys® matters.

III. Defendants' Position[8]

A. An expedited schedule is not justified

ARI originally proposed a schedule setting trial in August 2025, cascading impossibly tight deadlines and omitting rounds of expert reports under the guise of a potential preliminary injunction threat. *See* ECF No. 18-1. ARI now seeks to add a second—allowed, but unissued—patent to the case, and offers an updated schedule that postpones the trial by merely a month (in early September 2025). ARI's new schedule is even less realistic than its original schedule, for the reasons described below. Ultimately, ARI threatens preliminary injunction proceedings regardless of the pace of the schedule, so it makes no sense to use a schedule that is so rushed that it jeopardizes the Court's ability to effectively resolve the issues.

ARI's rushed schedule—which requires a trial in just over ten months, despite attempting to add yet another patent to the schedule (which has yet to even issue)—serves no purpose, decreases judicial efficiency, unnecessarily burdens Defendants, stifles proper fact discovery, undermines proper expert discovery and does not avoid the potential for injunction proceedings that ARI so emphasizes. On the contrary, despite proposing a rushed schedule, ARI nonetheless admits that it "will need to seek a preliminary injunction against all Defendants that are not subject to a 30-month stay," irrespective of whether its truncated schedule is entered. *See* Section II.A.

ARI's proposed schedule, though abridged, still does not guarantee that preliminary injunction proceedings will be averted. This is because at least some of Defendants' ANDAs were on file by June 2024, and FDA represents that it will take its initial action—which may include final approval—ten months after submission of the ANDA.[9] Ten months from June 2024 is April 2025, which is months before ARI's proposed September 2025 trial date.

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[8] Defendant Fresenius Kabi USA, LLC does not join Defendants in the above-captioned matters with respect to this joint letter given its pending pre-motion letter regarding Fresenius' anticipated motion to dismiss. *See* Fresenius' Pre-motion Letter, *American Regent, Inc. v. Fresenius Kabi USA, LLC*, No. 2:24-cv-07801-BRM-CLW (D.N.J. Sept. 3, 2024), ECF No. 12. Due to the nature of Fresenius' request and anticipated motion, it is respectfully submitted that Fresenius is unable to join in this letter or otherwise proceed with scheduling or substantive issues until the issues raised in the pre-motion letter are resolved.

[9] These representations are referred to as goal dates, or "GDUFA" dates. *See, e.g.*, https://www.fda.gov/industry/generic-drug-user-fee-amendments/gdufa-ii-submission-review#:~:text=Original%20ANDAs&text=Within%2010%20months%20of%20submission%20date.&text=Within%208%20months%2C%20provided%20the,*.

ARI is aware of the status of each of Defendants' ANDAs, including when each Defendant's ANDA will be eligible for final approval.[10] Importantly, although ARI is in possession of this information, the Defendants are not aware of the status of each other's ANDAs, as the Defendants are competitors and this information is confidential. Because the circumstances of each Defendant's ANDA approval status are different and dependent on the contents of each Defendant's ANDA, the logistics of any potential preliminary injunction proceedings should be dealt with on a Defendant-by-Defendant basis, separate from the case schedule. *See* Section III.B, *infra*.

ARI cites to a similar schedule set in the *Sumitomo* case, which ARI posits has "similar positioning" (*see* Section II.A). This is incorrect. *Sumitomo* was a unique situation where full litigation had already occurred on the drug at issue, and an accelerated schedule was entered to litigate only the second-wave method of treatment patents before a permanent injunction from the original litigation was set to expire. *See, e.g.*, *Sumitomo*, C.A. No. 18-cv-02065, ECF No. 8 (D.N.J. Mar. 20, 2018) at 1. Consequently, *Sumitomo* was able to avoid preliminary injunction proceedings.[11]

Additionally, ARI seeks expedited relief from this Court without moving with urgency itself. First, the Orange Book indicates that the patent at issue in this case, U.S. Patent No. 11,998,565 (the "'565 patent"), was submitted to FDA for ARI's selenious acid product on June 7, 2024. The Complaints in this case reveal that ARI received Notice Letters dated as early as June 10, 2024. Yet ARI waited until July 16, 2024, before bringing suit, despite knowing at that time that most ANDA applicants were not subject to a 30-month stay. Then it waited approximately another six weeks before proposing a schedule, while demanding that the thirteen Defendant groups respond less than two business days later and before some Defendants had even answered the Complaint. ARI also delayed weeks after the parties met and conferred before providing its draft portions of this letter, its revised schedule, telling Defendants it is receiving another patent it plans to assert in this action, and providing yet another revised schedule.[12] Thus, it has been 4.5 months since ARI received Defendants' notice letters, and ARI has hindered resolution on the parties' schedule negotiations with its shifting positions. Moreover, at the time ARI circulated its proposed schedule, it failed to circulate a Joint Discovery Plan—and has not circulated a Joint Discovery Plan to date. Thus, the parties have not even begun to discuss any discovery-related

[10] ARI's representation that Defendants' ANDA approvals "may happen at any time" (*see* Section II.A) is therefore disingenuous, because no Defendant currently has a goal date that allows FDA to immediately approve its ANDA.

[11] The trial was set for December 2018, and the injunction was set to expire in January 2019. *Id.*; *see also Sumitomo*, C.A. No. 18-cv-02065, ECF No. 25 (D.N.J. Apr. 19, 2018). All parties ultimately settled before trial.

[12] ARI's attempt to add another patent to this case—yet largely maintain its rushed schedule—further demonstrates the inappropriateness of ARI's proposed schedule.

issues. Yet, ARI now seeks to have trial in approximately 10.5 months. ARI should not be permitted to run both this Court and Defendants ragged when it has gone about this case in a leisurely manner to this point.[13]

While Defendants agree that district courts have the authority to manage their dockets efficiently, the best way to conserve judicial resources is by adopting Defendants' schedule, which proposes aligning this case's schedule with the Tralement®/Multrys® litigation involving overlapping patents, as described in Section III.C, *infra*.

B. Deadlines regarding any at-risk launch notice are not warranted

ARI's request that the Court order Defendants to reveal highly confidential, Defendant-specific competitive information on ARI-s one-size-fits-all timeline should be rejected. These arbitrary deadlines are not appropriately part of the case schedule. Whether a Defendant's ANDA is poised to receive FDA approval, whether a Defendant ultimately decides to launch at-risk, and whether a Defendant agrees to give advance notice of any such launch to ARI and/or the Court are all Defendant-specific questions, depending on the specific technical contents of each Defendant's ANDA. Defendants may not even know by ARI's arbitrary dates—occurring just weeks away—whether they intend to launch their respective products upon obtaining FDA approval. Defendants should not be forced to make premature decisions, and ARI's attempt to build additional requirements into the case schedule is inappropriate.[14]

In any event, Defendants are under no legal, statutory, contractual, or regulatory obligation to notify ARI of an intended at-risk launch. Neither the local rules nor federal rules contemplate any such obligation. *See Hoffmann-La Roche Inc. v. Teva Pharms. USA, Inc.*, No. 11-3635, ECF No. 124, at 1 (D.N.J. Feb. 5, 2013) ("Although this Court recognizes that it has discretion to manage its docket, the Court finds that Teva has no obligation to provide notice of its intent to launch its generic version of Xeloda® at risk – which is indisputably confidential, sensitive business information. . . . Further, the Court is not persuaded by Roche's arguments that the Court has the authority to order advance notice of its intent to launch in the absence of an agreement by Teva."); *AstraZeneca LP v. Breath Ltd.*, No. 08-1512, ECF No. 86, at 2-3 (D.N.J. Sept. 8, 2009) ("AstraZeneca's letter application, in which it sought to have the Court enter an order directing that Defendant Breath Limited ("Breath") be ordered to provide advance notice of any anticipated launch of, or any launch plans concerning, its proposed budesonide inhalation suspension products

[13] Indeed, if ARI truly wished to expedite this case due to a need for a preliminary injunction, there are many things it could have done, such as producing documents that it would need to justify a preliminary injunction, including its commercial documents supporting any claim of irreparable harm. Again, it has chosen not to do so.

[14] Additionally, Defendant Eugia notes that these Plaintiff's proposed deadlines should not apply to Eugia irrespective of the other Defendants given the statutory 30-month stay applicable to Eugia.

that are the subject of this litigation, is denied for the reasons set forth in the record of these proceedings, including because the Court does not believe it has legal authority to grant such relief."). Even ARI's case law "observed the principle that the generic defendants would not be required to provide notice of intent to launch at risk." *Otsuka Pharm. Co., Ltd. v. Torrent Pharms. Ltd., Inc.*, 99 F. Supp. 3d 461, 471-72 (D.N.J. 2015).

ARI's request goes beyond asking the Court to manage its docket and invades the competitive commercial market.[15] Other courts have recognized that adopting deadlines like ARI requests here "should not [be] lightly order[ed]" because it may harm Defendants' business interests by forcing them to reveal sensitive commercial strategies to competitors, including ARI and other Defendants, which may dissuade investors and stakeholders thereby damaging Defendants competitive position. *Allergan, Inc. v. Teva Pharms. USA, Inc.*, No. 2:15-CV-1455-WCB, 2017 U.S. Dist. LEXIS 136445, at *8-11 (E.D. Tex. Aug. 25, 2017) ("While recognizing that the Court's jurisdiction may extend to matters such as orders for advance notice of launch plans, the Court is cognizant of the prudential limitations on the exercise of that jurisdiction. Launch dates are highly confidential and important commercial information. The Court should not lightly order parties to disclose such information to their competitors. Additionally, it could dissuade investors and stakeholders, damaging Defendants' market position and undermining research and development efforts.").

Finally, if the Court were to grant ARI's proposal, it would force Defendants who may be merely contemplating a launch, when or if they obtain FDA approval, to expend fees and costs of defending a preliminary injunction motion before the issue is ripe. Suppose a Defendant does not obtain FDA approval or is contemplating a possible launch upon approval but ultimately decides against it. Under ARI's approach, the Defendant would have been forced to spend valuable resources defending against an unnecessary motion causing further competitive damage due to wasteful allocation of time and resources.

ARI has provided the Court no reason to disregard Defendants' commercial interests in this case; its request should be denied.

C. These Actions significantly overlap with the co-pending litigation related to Tralement® and Multrys®

In order to promote party and judicial efficiency, Defendants have proposed a schedule under which the instant case catches up to and aligns with the schedule that has been set in the preceding Tralement® and Multrys® case. *See* Case No. 24-cv-1022-BRM-CLW (Consolidated) at ECF No. 38. This is already quicker than a normal Hatch-Waxman schedule, and it offers the benefits of coordinating litigation on the same patent and subject matter, instead of duplicating the

[15] Notably, Defendants are already obligated by this Court to give notice of any FDA decision concerning ANDA approval. *See* L.P. R. 3.6(j)(requiring that defendants produce correspondence with FDA to plaintiffs within seven days of receipt).

Court's and the parties' efforts. ARI's proposed schedule, on the other hand, will result in significant inefficiencies and multiple trials on the same subject matter, and it should be rejected.

This case currently involves a single patent—the '565 patent—which is already being litigated in the co-pending Tralement® and Multrys® litigation. ARI primarily focuses on the unremarkable point that the instant cases and the co-pending Tralement® and Multrys® cases involve different ANDAs, different products, and some non-overlapping defendants. But ARI only pays mere lip service to numerous similarities between the cases, the most salient of which being that ***both sets of cases involve the '565 patent***. A significant portion of each case will involve invalidity of the '565 patent, which does not depend on the ANDAs or accused products involved in each case. In addition, ARI has indicated that it wishes to add its new patent to this action, and the Tralement Defendants also in this case expect that ARI will also attempt to add it to the Tralement®/Multrys® litigation. If ARI's new patent is added to both litigations, half of the asserted patents would be common across the two sets of cases.[16]

Patent No.	**Asserted in Tralement®/Multrys® cases?**	**Asserted in the instant matters?**
11,786,548	Yes	No
11,975,022	Yes	No
11,998,565	Yes	Yes
App. No. 18/672,876	Expected to be requested to be added	Requested to be added

While ARI notes that there are two other patents in the Tralement®/Multrys® litigation (U.S. Patent Nos. 11,786,548 and 11,975,022) that are not in this case, these patents are related patents from the same patent family and claim priority back to the same provisional application.[17] Accordingly, there is significant overlap in prior art and invalidity arguments across both litigations.

While ARI points out that there are some different defendants involved in the various cases, they fail to meaningfully address that there are five defendants involved in both sets of cases: Somerset, RK Pharma, Cipla, Gland, and Accord. For at least those defendants (not to mention the Court), under ARI's proposal, they face the unfair and inefficient prospect of having to litigate and decide the validity of the ***same patents*** in ***different cases*** and on ***different schedules***.

The only other distinction ARI points to is the status of 30-month stays and the risk of potential preliminary injunction proceedings. But, as explained above, ARI's proposed schedule

[16] ARI is continuing to prosecute continuation applications as well and the possibility exists that yet additional overlapping patents will be asserted in each case.

[17] Specifically, U.S. Patent No. 11,786,548 is the parent to both the '565 patent and U.S. Patent No. 11,975,022.

does not alleviate the potential for preliminary injunction proceedings, thus rendering this a distinction without a difference. The most efficient course is the one charted by Defendants to align the schedule in this case with the Tralement® and Multrys® cases so that all the cases may proceed in an orderly and efficient manner.

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The parties are happy to provide additional information regarding the above issues should the Court so desire.

Respectfully submitted,

s/*Charles H. Chevalier*
Charles H. Chevalier

cc: Counsel of Record (via ECF and e-mail)